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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Frederic Beseme

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ALEXANDRIA, VA 22320-4850

EXAMINER

MARVICH, MARIA

ART UNIT

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1633

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/717,580	Applicant(s) BESEME ET AL.	
	Examiner MARIA B. MARVICH	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,6,10,20-23,30,36,39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) 21-23,30 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6,10 and 20 is/are rejected.
- 7) ☒ Claim(s) 39 and 40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/446,024.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 2, 5, 6, 10, 20-23, 30, 36, 39 and 40 are pending in this application. This office action is in response to an amendment filed 2/29/08. Claims 21-23, 30 and 36 are withdrawn and therefore, claims 1, 2, 5, 6, 10, 20, 39 and 40 are under examination.

Election/Restrictions

This application contains claims 21-23, 30 and 36 drawn to an invention nonelected with traverse in the reply filed on 6/11/07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections

Claims 1 and 2 are objected to because of the following informalities: claim 1 recites “comprising the nucleotide sequence, which in the form of DNA, is set forth in SEQ ID NO:11. SEQ ID NO:11 is a DNA sequence and the RNA complement forms the retroviral RNA molecule. Claim 1 would be clearer if written as --comprising the RNA complement of SEQ ID NO:11--.

Claim 2 recites that the RNA molecule comprises “a nucleotide sequence encoding a functional part of SEQ ID NO:11”. SEQ ID NO:11 is a DNA sequence that is not technically encoded by an RNA molecule. It appears the claim intends --a nucleotide sequence comprising the RNA complement of a functional part of SEQ ID NO:11--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a NEW rejection.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation *United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988). Whether undue experimentation is required is not based upon a single factor, but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) and include the following:

SEQ ID NO:11 is the DNA complement of RNA that is a member of human endogenous retroviruses. The instant claims are drawn to a retroviral RNA molecule that is the complement of SEQ ID NO:11 and as part of a diagnostic composition. The specification discloses that SEQ ID NO:11 is a reconstructed putative genomic RNA from smaller clones detected by screening a cDNA library with Ppol- MSRV probes (see Figure 1). SEQ ID NO:11 encodes a structure of R-

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U5-gag-pol-env-U3-R, which is found on multiple chromosomes (see paragraph 0002).

Applicants have aligned the reconstructed sequence with the genomic clone and found that it exhibits 96% similarity with two discontinuous regions of genomic clone RG083M05 where it is integrally. From this alignment, the Applicants have deduced an LTR sequence and identified elements characteristic of retroviruses. Applicants have called this sequence HERV-W. The specification discloses one sequence of SEQ ID NO:11 as well as shorter sequences that were used to deduce the sequence of SEQ ID NO:1 for the claimed sequences that exhibit homology to SEQ ID NO:11.

HERVs are human endogenous retroviruses that are a family of viruses within our genome with similarities to present day exogenous retroviruses. Near the time the invention was made, Urnovitz and Murphy reviewed human endogenous retroviruses (HERV) (Clinical Microbiology Reviews, 1996, Vol. 9, No. pages 72-99). Urnovitz and Murphy teach that HERV proteins are expressed in vivo and cause detectable immunologic responses to putative HERV-encoded antigens (see page 86, right column, for example). Urnovitz and Murphy teach that placental HERV products may be expressed as antigens. Urnovitz and Murphy also teach that there may be a correlation between antibodies specific for virus protein p30 in umbilical cord blood serum and complications during pregnancy (see page 87, left column, 1st paragraph, for example). Antigens that are related to the p30 protein in teratocarcinomas have been documented, however Urnovitz and Murphy teach that it is uncertain whether members of the HERV family encode these p30 like antigens. Urnovitz and Murphy caution that whether such antigens elicit autoimmune activity warrants careful documentation (see page 87, right column).

In the instant case, designation of SEQ ID NO:11 as a diagnostic is highly unpredictable given the lack of guidance in the specification as how to use SEQ IDNO:11 which is exacerbated by the art which teaches that the establishment of a molecule as a diagnostic is a highly unpredictable art. The instant specification is limited to conjecture as to potential disorders that HERV-w might be associated. The specification suggests that the sequence can be a molecular marker for an autoimmune disorder, or a molecular marker for a pathology that is associated with a pathological pregnancy, or a chromosomal marker for susceptibility to an autoimmune disease. Further, applicants disclose that a nucleotide fragment would be useful as a diagnostic composition, such as in diagnostic hybridization techniques (see paragraph 0078). Specifically, the specification discloses that the HERV-W is expressed in placenta, but merely speculates about the function in placenta and suggest that expression of the HERV-W in the placenta may be under the control of isolated LTR and may result in pathology from aberrant expression. Applicants speculate on a fusogenic role at the level of cellular subtypes in the placenta, an immunosuppressive role and a protective role (see paragraph 0008-0010). There is no description of how the structure of the putative genomic RNA sequence identified as SEQ ID NO:11 relates to the proposed functions. Beyond expression in the placenta, and identity to gene encoding retroviral env, pol and gag sequences, the specification has not described characteristics or specific regions of SEQ ID NO:11 that would provide a correlation between structure and function. It is not clear if wild-type HERV-w is to be associated with the disorder or if another yet unidentified mutant version of HERV-w is. Nonetheless such ability to distinguish between pathological states and normal, healthy states would require an identification

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of what distinctions exists in HERV-w in each state. None such criteria or direction or guidance is provided in the art or specification.

The art of developing markers for diseased states is a highly unpredictable art. Potential probes require validation on a large collection of clinical specimens whereas applicants have collected data from three samples of which the actual nexus between disease state normal tissues is not clear in general. Pollack, page 280, col 2 for a discussion of such work in tumor cells, which hover, is generic to any number of diseases.

Given the above analysis of the factors which the Courts have determined are critical in ascertaining whether a claimed invention is enabled, it must be considered that the skilled artisan would have had to have practiced undue and excessive experimentation in order to practice the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 5 and 6 are rejected under 35 USC 102(b) as being anticipated by AC000064 as evidenced by the alignment of AC000064 and SEQ IDNO:11 and .

Applicant cannot rely upon the foreign priority papers to overcome this rejection because

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a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

AC000064 comprises multiple functional parts of SEQ ID NO:11 as evidenced in the alignment attached. These regions overlap protein coding regions as well as regulatory regions.

Claim 10 is rejected under 35 U.S.C. 102(e) as being anticipated by Holland et al (U.S. Patent No. 5,686,247; see entire document

Holland et al teach a number of primers that comprise at least a nucleotide sequences (dinucleotide) that will bind to SEQ ID NO:11. For example SEQ ID NO:s 1-10 are primers designed to bind to HERV-K10, which given similarities and the undefined nature of highly stringent conditions should be able to bind to SEQ IDNO:11.

Conclusion

Claims 39 and 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD
Examiner
Art Unit 1633

/Maria B Marvich, PhD/
Examiner, Art Unit 1633